AMCP Submits Comments on PDUFA

On Oct. 28, AMCP submitted comments to the FDA on the reauthorization of the Prescription Drug User Fee Act (PDUFA), focusing on the use of real-world evidence (RWE) for regulatory decision-making and cell and gene therapies. AMCP supports the FDA's proposal to establish a pilot program to identify approaches to generating RWE that can meet regulatory requirements in support of labeling or for meeting post-approval study requirements. However, AMCP cautioned that submission of RWE should not be in lieu of confirmatory clinical trials for drugs approved through accelerated approval pathways. AMCP also supports the FDA's proposal to strengthen staff capacity in the Cell and Gene Therapy Program in order to meet increasing demands for review and approval of emerging cell and gene therapies.

Read AMCP's comments.

Eye On Washington

AMCP Joins Influenza Antiviral Sign-on Letter

On Oct. 28, AMCP joined a pharmacy stakeholder coalition letter to HHS requesting authorizations for pharmacists to order and administer antiviral medications and flu tests. The stakeholders cited public health experts' concerns that relaxation of COVID-19 mitigation efforts could lead to a spike in influenza cases this winter. Pharmacists can help reduce unnecessary strain on the health care system by ordering influenza tests and initiating treatment.

Read the full letter.

AMCP Joins COVID-19 Antiviral Recommendations Sign-on Letter

On Nov. 2, AMCP joined a pharmacy stakeholder coalition letter to CMS requesting the agency use its PREP Act authority to establish payment mechanisms for Medicare and Medicaid to reimburse pharmacists for COVID-19 patient assessment services. On Sept. 13, HHS authorized pharmacists to order and administer treatments for COVID-19. However, Medicare and Medicaid beneficiaries may be unable to access oral antiviral therapies for COVID-19 because of reimbursement barriers. The coalition suggested several options CMS could take to establish a payment mechanism, including identifying existing CPT codes for patient assessment services or establishing emergency G codes that are reimbursable for pharmacists' patient assessment services to support ordering of COVID-19 therapeutics.

Read the full letter.

Advocacy Tip

Stay up-to-date: Read AMCP's Letters, Statements and Analysis on all legislation and regulation impacting managed care pharmacy.

President Biden Signs Infrastructure Investment and Jobs Act

Earlier this week, President Biden signed into law the Infrastructure Investment and Jobs Act (H.R.3684), which injects $1.2 trillion into transportation, broadband, and utilities over a five-year period. To offset costs, the law restores the two percent cut, also known as the sequester, to all Medicare payments beginning in 2022, which Congress paused at the onset of the pandemic. These cuts run through 2031 at an estimated savings of $21 billion over 10 years. The law further delays the Medicare Part D rebate rule until 2026, resulting in $52 billion in savings over the three-year delay period. Finally, beginning in 2023, the law requires drug manufacturers to refund Medicare quarterly for unused medications in single-dose or single-use packages dispensed under Medicare Part B, resulting in $3.2 billion in savings.

President Biden To Nominate Dr. Robert Califf for FDA Commissioner

On Nov. 12, President Biden announced his intention to nominate former FDA commissioner Dr. Robert Califf to the same post. Dr. Califf is a cardiologist and experienced clinical trialist who founded the Duke University Clinical Research Institute. He previously served as FDA commissioner during the last year of the Obama administration in 2016.

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